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Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design

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Abstract

Introduction: To optimize children's health and development, Finland has called for settings approach and a change of direction in child and family services. The Let's Talk about Children (LTC) approach, brief psycho-educational discussions for parents with kindergarten- and school-age children, has been implemented across most Council of Oulu Region's municipalities over the past three years. This study protocol describes the Let's Talk about Children Evaluation (LTCE) Study, a community- and family-level intervention across 30 municipalities in northern Finland, the process of the renewal, and the methods used to evaluate its effectiveness in improving children's socio-emotional well-being.

Methods and analysis: A quasi-experimental ecologic study protocol will be implemented to evaluate whether universal LTC approach improves children's well-being. In each municipality, a series of actions will be conducted over periods of municipal engagement, training of personnel, and implementation of the LTC approach in all communal child and family services. Data collection consists of yearly online questionnaires for local management groups and retrievals from the population statistics and child welfare statistics of Finland. Child and family service data includes annual numbers of LTC discussions and LTC network meetings. Outcome measures include annual child welfare notifications, interventions and placements outside home, as well as referrals to child and young person psychiatric clinics during the years 2014 -2018.

Ethics and dissemination: The study design has been approved by the management of Oulu University Hospital according to the guidelines given by The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. All data are treated and implemented according to national data security laws. Study findings will be disseminated to provincial and municipal partners, collaborative community groups and the development research community. The LTCE Study databases will guide future regional development action and policies.

Strengths and limitations of this study

- The Let's Talk about Children Evaluation (LTCE) Study is study protocol is suitable in cases where the intervention is implemented year by year across real-life municipalities. By creating a regional database of Let's Talk about Children (LTC) results, we can sample more than 100 000 children and youth. There is high merit in large scale evaluations such as this.
- The LTC-approach seeks to better link community services provided to families and to assist families in accessing needed supports.
- An adequate measurement of an individual-level LTC-intervention is difficult, because the framework of strengths and vulnerabilities is underlying both the capacity of individuals and their social and physical ecologies.

Introduction

Children's mental health problems disrupt healthy development and are among the leading causes of disability for children and youth. There are opportunities, however, to improve mental capital through different types of intervention. We can make efforts to build the cognitive and emotional resources that influence how well an individual is able to experience a high quality of life. On the other hand, the problems extend beyond an individual to family members and communities. Thus, system-wide changes and setting approach are needed [1, 2]. The emergence of a settings approach has been attributed to the Ottawa Charters (WHO, 1986) statement that health is created and lived by people within the settings of their everyday life. More research into system interventions is needed to produce evidence base to transform child and family services.

Many evidence-based interventions fail to take an ecologic perspective in order to achieve a population-level impact. Children's problems may develop as a result of problems within their families or communities and may include parental mental health problems, food and housing insecurity, or exposure to dangerous

neighborhoods or challenging schools. Intervention may be more effective when directed to the underlying issues and designed to fit the work flow and staffing of local child and family services [3]. Integration efforts in Finland involve work with school-based and public health services. Health promoting activities will be delivered in the context for co-occurring service conditions, and with a focus on individual and family strengths and vulnerabilities.

A strategic approach to health promotion consist both vertical and horizontal actions. In this way strong systems of local child and family services with universal delivery can be achieved. For the moment, service systems are often expensive in terms of duplication, inefficiency, and high procurement costs [4]. In developing child and family services, the challenges include the fragmentation of services, inter-sector boarders, different work cultures, and data transmission difficulties. Furthermore, the families have a wide diversity of needs, as well as differences in obtaining assistance and advice.

In planning the present development program, the following framework was used to conceptualize the integration of child and family services. Activity integration involves joint provision of intervention by different sectors of services and joint training sessions for professionals. At regional level, policy integration includes the development of a harmonized incentive structure for operationalizing the actions and a formation of a new partnership for municipal-based delivery of child and family services. Furthermore, capacity building includes strengthening the evaluation of health promotion activities among municipal child and family services.

The present development program across the Council of Oulu Region is based on elements of brief psycho-educational discussions with parents (Let's Talk about Children, LTC) [5]. LTC was developed for the Effective Family Program and has been tested in real life mental health clinics to fit in the real life settings of multi-professional child and family services [5-7]. In Finland, most children are happy with their lives. Not all children, however, are getting the best possible start in life. Almost 10% of children live in jobless households. Among secondary school aged children 4 % see their parents drunk on a weekly basis, 7 % of children report being weekly bullied in school, and 8 % do not have close friends [8].

The objective of this paper is to describe the protocol of a quasi-experimental ecologic study with a municipal group and multiple time-series design. We will evaluate the effectiveness of a community level intervention across all public child and family services in 30 municipalities in in the Council of Oulu Region to promote socio-emotional well-being of children. The intervention will identify children's needs and provide support to them among broad spectrum of arenas in which support may be effective. The intervention is expected to produce positive aspects of child development and is impacted through changes to children's nearest social and physical ecologies. We intend to assess the associations between change in annual coverage of LTC actions and change in different outcome measures among age groups residing in urban and rural municipalities. The intervention is expected to improve children's well-being after each municipality implements the LTC activities in all child and family services. It is also anticipated that changes will be observed in incidents of emergency placement or taking into care of a child as well as incidents of new referrals to child or adolescent psychiatric unit.

Methods and analysis

Design

The present study is an ongoing quasi-experimental ecologic study, which is conducted in a naturalistic setting of public child and family services in the Council of Oulu Region, Finland. The study focuses on the population under the age of 18 years. We assess the ecologic association between the average LTC-intervention activity and the aggregated measurement of the rate of unwanted incidents among multiple children groups. The sources of data used involve observations of multiple groups based on place and time (Figure 1). The evaluation will consist of data collection at five time points (baseline and following each of the four data collection).

Figure 1 Design of the present study. Blocks of municipalities represent group of intervention areas. Each time period (T0, T1, T2, T3, or T4) represents a data collection point. Each unit (control or intervention) represents one time period of one block of municipalities.

Insert Figure 1 in here

Since 2012, the LTC-services have been applied in prior municipalities. The training stage of LTC-intervention among service suppliers was first conducted in the town of Raahe. During the study, the LTC-intervention will be rolled out gradually to 30 municipalities (see participants below). The LTC intervention activities will be branching out gradually year by year (Figure 2). The intervention will be fully implemented by the end of the study, with all municipalities receiving the intervention.

Figure 2 Data collection timeline for the Let's talk about the children evaluation study.

Insert Figure 2 in here

Participants

"Change now. Let's talk about the children at the Council of Oulu Region" program is coordinated by the Northern Ostrobothnia Hospital District. The program was planned both at regional and local levels within regional offices, local public sector offices, non-governmental organizations, and other regional partners. The program coordinators will operate in order to guide the activities at local level. At local level, the integration will be conducted among the implementers, including municipal employees and relevant community-based partners. Interventions will be made in early childhood education in primary school, and in secondary school as well as in all health and social services.

The evaluation study is being conducted by the Oulu University Hospital in close liaison with the University of Oulu and the University of Lapland. The Oulu University Hospital received circa 250,000 € funding for the implementation of LTC services from member municipalities of the Northern Ostrobothnia Hospital District and the Council of Oulu Region (European Regional Development Fund). The hospital district consists of 30 distinct municipalities, of which three are urban (Kempele, Oulu and Raahe), five are rural close to urban areas (Ii, Liminka, Lumijoki, Siikajoki and Tyrnävä), 10 are core rural (Haapajärvi, Haapavesi, Kalajoki, Muhos, Nivala, Oulainen, Pyhäjoki, Reisjärvi, Sievi and Ylivieska) and 12 are sparsely populated rural (Alavieska, Hailuoto, Kuusamo, Kärsämäki, Merijärvi, Pudasjärvi, Pyhäjärvi, Pyhäntä, Siikalatva, Taivalkoski,

Utajärvi and Vaala). The classification of municipalities will be described further in context with statistical analyses.

Multiple children groups by citizenship

Complete numbers of children and young people are retrieved from the Population Statistics (Statistics Finland) and the numbers are sorted by municipalities of the Council of Oulu Region. Population data by age group gives the municipality's permanent resident population in each age group on the last day of the year. The multiple age groups evaluated in the study are 0-6-year-olds, 7-16-year-olds, and 0-22-year-olds. A description of the multiple groups and measures used in the data collection is reported in Table 1.

Insert Table 1 in here

Table 1. A description of study population and measures used in the data collection, year 2013.

Area	Population*		Child welfare actions			Home help ˢ	Psychiatric referrals	
			Notification**	Intervention ***	Placement ****			
	aged 0 - 9 n	10 - 19 n	aged 0-17 n	0 – 17 n	0 – 17 n		0-17 n	13-22 n
Alavieska	348	406	65	48	7	0		5
Haapajärvi	1020	1106	132	190	21	20	8	12
Haapavesi	976	1065	77	108	18	0	3	4
Hailuoto	80	87	19	11	0	0		1
Ii	1584	1311	161	209	7	19	11	5
Kalajoki	1647	1605	125	66	21	8	1	1
Kempele	2852	2496	428	264	32	54	19	9
Kuusamo	1649	1887	137	233	49	89	3	7
Kärsämäki	323	367	47	97	12	9	2	1
Liminka	2351	1708	248	120	10	31	11	7
Lumijoki	435	324	46	126		14		3
Merijärvi	178	179	13	8	0	0		
Muhos	1550	1361	165	127	20	52	8	9
Nivala	1803	1606	284	275	34	0	6	6
Oulainen	999	1078	164	106	19	0	6	3
Oulu	26476	23337	4822	3719	672	860	110	105
Pudasjärvi	890	1036	103	121	21	0	4	3
Pyhäjoki	408	406	64	36		6	7	
Pyhäjärvi	574	587	107	123	16	6	3	2
Pyhäntä	211	234	25	7		0		4
Raahe	3354	3183	570	321	80	60	19	12
Reisjärvi	380	404	76	59	8	9		
Sievi	952	911	122	132	13	0	1	3
Siikajoki	848	790	136	83	20	10	8	3
Siikalatva	613	677	62	74	10	0	4	5
Taivalkoski	438	552	46	40	17	0	2	3
Tyrnävä	1562	1076	156	139	9	1	3	6
Utajärvi	319	360	48	82	10	0	5	2
Vaala	254	365	117	59	17	22	7	6
Ylivieska	2182	1869	290	326	39	0	7	12
Total	***57256***	***52373***	***8855***	***7309***	***1182***	***1270***	***258***	***239***

* Population by age group, year-end total
** The numbers of child welfare notifications
*** The numbers of child welfare interventions and in community care
**** The numbers of placements outside the home.
ˢ Home help, recipient families with children

Intervention

The primary objective of the Let's Talk about Children intervention is to prevent mental health problems of children and adolescents. We aim to promote health by making changes in modifiable risk conditions as

well as bringing supportive changes in attributes that help children grow and develop successfully. At system level, LTC development program also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of that system to maintain LTC activities and to catch risk conditions before they get worse. The intervention will then provide resources and support to initiate local activity program, ultimately aiming for the LTC discussions and network meetings to become self-sustaining over time.

At local level, the intervention will be implemented and coordinated by a Local Management Team (LMT). The LMT includes managers of early childhood education, primary school, health services and social services. Each LMT is responsible for implementing the LTC interventions in the child and family services of the municipality. It is necessary to have different LMT for each area due to the large number of service units (kindergartens, schools, health and social care centers), and because the units are spread across the whole county. No one LMT is of sufficient size to cover the whole county.

Each municipality will receive a “municipal engagement phase” for four months prior to the local trainers’ training (Figure 2). During this phase, the LMT will engage with the elected member structures, schools and other units in the LTC intervention activities. The program will then deliver the trainers’ training sessions of LTC discussion and network meeting. These training sessions will be subsidized using program resources. The LMT will coordinate trainers’ training by finding suitable participants. Furthermore, the LMT will advertise the LTC activities using local media (e.g., newspapers, posters and leaflets). The local trainers will all deliver training sessions of LTC discussions for their colleagues in the units of ongoing municipal child and family services.

Each LMT is given strategic support as well as a clear framework and timescales around the assessment of the local activities and outcomes. The Oulu University Hospital will coordinate year by year the intervention activities led by the LMT. Furthermore, appropriate specialist support and mentoring will be provided to help the LMT in collecting data and sustaining the local units in their LTC intervention activities. All the LMTs are responsible for the implementation and continuity of the universal LTC activities with the parents.

At family level, the intervention will include provision of universal LTC discussion for parents and LTC network meeting for parents wanting to have support.

The LTC discussion

This parent-focused method has been described earlier [9]. Briefly, the aim of the LTC discussion is to help parents recognize their children's strengths and vulnerabilities and to inform parents of ways to support their children in spite of any problem in the family. The LTC discussion consists of one or two sessions with the parent or with both of the parents. It is carried out with the child's own teacher, nurse or social worker. The LTC manuals in Finnish are available in the internet for use in early childhood education, in primary school, in secondary school as well as in all health and social services [9].

When parents take up any problem the family is currently facing, for example poverty, unemployment and housing problems, there is an option for a further network meeting. With approval by the parents the meeting will be organized with those partners who are expected to be able to help the family.

The LTC network meeting

The LTC network meeting has been designed to respond to the different needs of the family on an ecologic base. Depending on the needs, representatives of services as well as the family's own network are invited in the meeting. The aim of the LTC network meeting is to activate all participants to provide support to the child and family. The meeting offers a joint action forum for the aid and social support that is needed [10].

In order to implement LTC activities one has to start by measuring it. On each municipality, the intervention will include measures on operational data of LTC discussions and LTC network meetings. From 2015 onwards, aggregated counts of LTC discussions and network meetings are obtained from each municipality of the Council of Oulu Region. We use a time-series design to compare years under different LTC-intervention intensity among age groups of 0-6 years, 7-16 years and 0-22 years.

Outcome measurement

We assess children's unwanted outcomes based on populations defined both geographically and temporally. Outcome measurements are averaged for the populations in each geographical or temporal unit and then compared using standard statistical methods. The primary analysis will compare the proportion of children referred to child welfare services between different intensity of LTC activities. Furthermore, the proportion of children referred to psychiatric clinics will be analyzed respectively. Secondary outcomes will be the proportion of children who report experiences of being in moderate or poor health, having experiences of inadequate parenting, moderate or severe anxiety, difficulties to talk to parents and feelings that teachers are not interested in how the pupil is doing.

Data sources

The follow-up of child and family service development will include items on commitment made by local organization, local management groups, trainers' training and local training of personnel. Program maintenance and sustainability will include items on how LTC activities are adopted into the regular activity of all child and family services and how LTC activities are maintained by local organizations. Problem-solving capability includes how to tackle children's health issues as an activity in its own and how participants work together in planning actions.

Online questionnaires will be sent out by e-mail to each local management group once a year, in January, and the respondents fill in the questionnaire themselves. Additional request are made until data from each participating municipality have been received. Then, the intervention phase (control phase, training and implementing phase, and constant actions) is recorded for each municipality at baseline and after each of the four following intervention periods i.e. calendar years.

In Finland, the municipalities are obliged to collect and report the child welfare data. Each year, the municipalities are sent a data request form where they are requested, within specified time, to log in the Lasu-Netti website and check the provided list of current placements, record any changes to placements,

and record data on support interventions in community care. The child welfare data are retrieved in electronic form and updated to the national database. The child welfare statistics have been compiled and processed by the National Institute for Health and Welfare since 1991.

In Finland, the nationwide School Health Promotion study monitors the health and well-being of Finnish adolescents. The School Health Promotion study is carried out every second year in March–April. Since 1996, comprehensive school children across 8th and 9th graders have been surveyed. For example, the questionnaire includes measures shown in table 2.

Table 2 In 2013, the School Health Promotion study monitored pupils' health across 8th and 9th graders of comprehensive school residing in the municipalities of the Council of Oulu Region. The number gives the proportion of children who experienced that way in relation to all those who responded to the survey (Sotkanet, Institute for Health and Welfare).

Measure	2013 %
Inadequate parenting (ind. 284)	17,6
In moderate or poor health (ind. 286)	16,2
Moderate or severe anxiety (ind. 328)	11,1
Difficult to talk to parents (ind. 329)	8,6
Teachers are not interested in how the pupil is doing (ind. 355)	58,0

The data are gathered by an anonymous and voluntary classroom-administered questionnaire. The questionnaire is continuously being developed. Still, most of the questions have remained the same for almost 20 years, so as to maintain comparability.

The child welfare notifications

The measurement gives the number of child welfare notifications filed during a calendar year. The notification is filed in a municipal unit responsible for civic social services. According to the Finnish Child Welfare Act, a child welfare notification is made if one notices or is informed of circumstances relating to the care and upbringing of a child that give rise to a need to assess the need for child welfare measures. It can be made by phone, in writing or by visiting the municipal office in person.

The child welfare interventions in community care

The measure gives the numbers of children receiving support as a community-based child welfare intervention during a calendar year. For example, the support intervention in community care comprises support for accommodation, livelihood, school attendance and hobbies of the child. The measure also includes children receiving support in community care before a placement. Before a child is placed outside the home, it is necessary to investigate what opportunities there are for the child to live with relatives or with other persons close to the child.

The placements outside the home

The measure gives the number of children who have been placed outside the home during a calendar year. The measure includes counts of children placed outside the home as a child welfare intervention in community care, counts of emergency placements of children, counts of children taken into care involuntarily and counts of children who receive after-care outside the home. Causes behind the placements outside the home can be related to parents, as well as to children. Substance use is often an underlying factor.

The referrals to child and young person psychiatric clinics

Oulu University Hospital provides treatment for the children in the Northern Ostrobothnia Hospital District and northern Finland. Referrals to the hospital are written with the intention that the patient will be assessed and treated in before responsibility is transferred back to the referring health professional or

general practitioner. Any hospital that receives referrals will need to capture information about these patients.

Home help

The data are collected by Statistics Finland from all municipalities annually by mid-February following the statistical year. The data on the activities and the volume of social services produced and purchased by municipalities are primarily collected with a web collection form through a data collection service. The conventional paper form is also available in case it is not possible to use the web form. From 2016 onward, this data collection will be transferred to the National Institute for Health and Welfare.

The LTC discussion and network meeting data

In each local unit, each professional keeps a record of LTC discussions held. Furthermore, each professional who convenes a LTC network meeting will keep a record. After each calendar year, all the Local Management Teams who have passed the community engagement phase are contacted by email and web survey form. The aggregated counts of LTC services are reported on each municipal child and family service sector. Data collection is coordinated by the office of Primary Health Care Unit of the Northern Ostorobothnia Hospital District.

Effect-measure modification

Home help rate, recipient families with children is a measure of yearly rate of families with children receiving home help by the municipal welfare services. The denominator is the number of households with at least one person aged under 18 in the same year (Statistics Finland). Home help includes for example assistance with activities related to personal care, child care and other daily activities of families. The data cover the services funded by municipalities, that is, services that the municipality has produced or paid for. The services that clients fund themselves are not included.

LTC intervention rate is a measure of yearly rate of children receiving LTC discussion by municipal child and family services. The denominator is the number of children in the same year.

The classification of municipals. The areal division by Finnish Area Research [11] reveals the differences in socioeconomic and endogenous development factors between the municipalities. It divides municipalities into four categories: urban areas (cities and towns); rural municipalities close to urban areas; core rural municipalities; and sparsely populated rural municipalities. ***Urban areas*** are the areas that form centers of high economic importance. In ***rural municipalities close to urban*** *areas*, residents have the chance to work in nearby towns and cities with highly diverse business life. These economically integrated rural municipalities have a high level of welfare. ***Core rural municipalities*** are situated close to a number of medium-large centers and most of the villages they contain are economically viable. ***Sparsely populated rural municipalities*** are characterized by long distances from municipal centers and have rapidly declining populations. To these municipalities the threat is a cycle of poor development: there are insufficient new jobs to replace the traditional jobs which are disappearing, young people move away, services disappear, and the capacity of municipalities for the economic management is low.

Data analysis

By calendar year, aggregated counts of child welfare notifications, child welfare interventions and in community care and child placements outside the home will be described for each municipality. Incidence rates and proportions for each event will then be computed by dividing the yearly counts by the year-end total population. By calendar year, respectively, incidence rates and proportions of referrals to child psychiatric clinics will be described for each municipality. The LTC intervention data are calculated by dividing the number of LTC discussions by the population eligible for the intervention. Then, for each municipality, LTC intervention data collected across all study periods will be classified in four categories according to the phase of the LTC implementation: control period, training in the LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions.

During the years 2014-18, altogether 500 000 person-years across the age-group 0-19 years will be followed. To summarize the relationship between LTC services and outcome variables we use descriptive contingency tables. Categorized LTC variable is tabulated for each outcome variable. The table is created to display data for any outcome measure (number of events and incidence rate) and subcategories of LTC services (control period, training in the LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions). Most of the LTC services are rendered among families with school-age children. Hence, similar analyses will be performed separating data into subsamples according to age. Stratified analyses will include age-groups 0-6, 7-16 and 17- 19 years.

For any given outcome, the regression analysis involves the group-specific incidence rates and the group-specific coverage data of LTC discussions. We will apply a log-linear model in the analysis of incidence rate-ratio estimation. The results of statistical analyses will be presented as incidence rate ratios with 90% confidence intervals and *p*-values.

Ethics and dissemination

The study design has been approved by the management of Oulu University Hospital according to the guidelines given by The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. The Regional Ethics committee has stated that this study does not need ethics approval.

Two rationales behind the present study design are: An adequate measurement of an individual-level LTC-intervention is difficult in real-life, because the framework of strengths and vulnerabilities is underlying both the capacity of individuals and their social and physical ecologies. In the Council of Oulu Region, furthermore, all the municipal authorities make autonomously decisions on the implementation of LTC-intervention. All data are treated and implemented according to national data security laws.

All the parents are offered the opportunity to have the LTC- discussion and given a written structure of the discussion themes. When agreed they will make an appointment with the professional. In natural setting of child and family services, written human subject consent is not necessary.

This paper has outlined the Let's Talk about the Children activities at the Council of Oulu Region evaluation study design and data collection, as well as details on the implementation of the intervention. The LTC evaluation study uses a quasi-experimental trial design to evaluate the effectiveness of a community-level intervention designed to increase children's well-being. The design is suitable in cases where the intervention cannot be delivered to all intervention areas at the same time.

Strengths of the study include the number of participating municipalities and the multiple data collection stages. The implementation of the LTC intervention in local child and family services may decrease the need for highly specialized child protection and child psychiatric services in northern Finland. The results from the study will contribute to the limited research available on the effectiveness regarding the promotion of children's well-being via an intervention program using child and family services approach as a whole.

This pragmatic evaluation of a community-led intervention in real-life multi-professional setting is expected to provide information on adapting evidence-based methods for diverse municipalities. The child and family services are often renewed and directed so, that there are little, if any, resources for program evaluation and outcome monitoring. In this study, independent regional investigators work together with local professionals to assess in real life settings the association between change in local LTC-intervention rate and change in ecologic measures of children's health.

The LTC evaluation study in the Council of Oulu Region aims to expand our knowledge on the effectiveness concerning the promotion of children's health via an intervention program using a multi-sectorial approach. At the same time we are developing co-operation between researchers and practitioners. The results can be useful to both the researchers and the managers leading the local reform of public child and family services. If the LTC intervention proves to be effective, the intervention program can be distributed in Finland and in other high-income countries.

List of abbreviations

LTCE = Let's Talk about Children Evaluation

LTC = Let's Talk about Children, a brief psychoeducational discussion with parents

LMT = Local Management Team

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Authors' contributions

VK and JJ obtained funding for the study. JJ further developed the intervention. VK designed the ecologic part of the study. HE and AP contributed to the study design. VK wrote this paper. All authors drafted and approved the final version of the manuscript.

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Competing interests: The authors declare that they have no competing interests.

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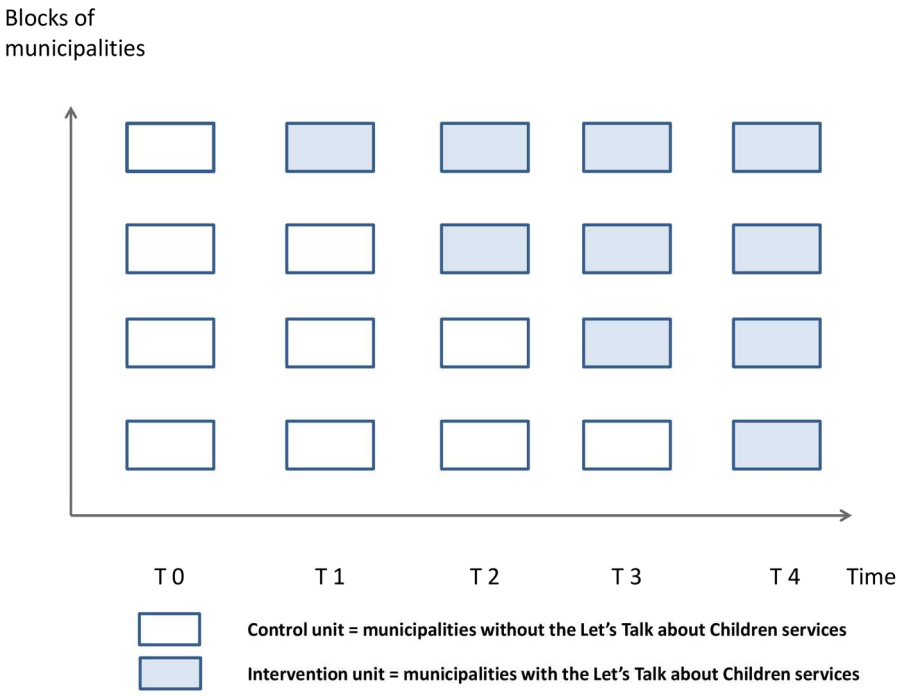

Figure 1 Design of the present study. Blocks of municipalities represent group of intervention areas. Each time period (T0, T1, T2, T3, or T4) represents a data collection point. Each unit (control or intervention) represents one time period of one block of municipalities.

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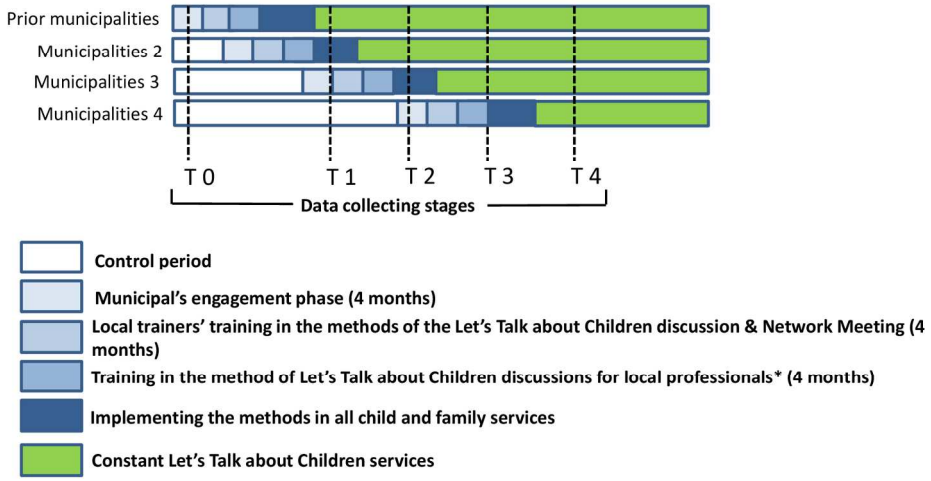

Data collection timeline for the Let's talk about the children evaluation study

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-10
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	n/a
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*12-14*
Bias	9	Describe any efforts to address potential sources of bias	14-15
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	15-16
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	

		(*e*) Describe any sensitivity analyses	Page no results are shown
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Ethics and dissemination			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	n/a
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18-19

BMJ Open

Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design

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Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design

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Abstract

Introduction: To optimise children's health and development, Finland has called for a settings approach and change of direction in child and family services. The Let's Talk about Children (LTC) approach, which consists of brief psycho-educational discussions with parents of kindergarten- and school-aged children, has been implemented in most of the Council of Oulu Region's municipalities over the past three years. This study protocol describes the Let's Talk about Children Evaluation (LTCE) Study, a community- and family-level intervention covering 30 municipalities in northern Finland; the process and the methods used to evaluate its effectiveness in improving children's socio-emotional well-being.

Methods and analysis: A quasi-experimental ecologic study protocol is implemented to evaluate whether universal LTC practices improve children's well-being. In each municipality, a series of measures concerning municipal engagement, training of personnel, and the LTC activity with parents are conducted in all communal child and family services. Data collection consists of annual online questionnaires for local management groups and the retrieval of information from Finland's population statistics and child welfare statistics. Child and family service data include annual numbers of LTC discussions and LTC network meetings. Outcome measures include annual child welfare notifications, interventions and placements outside the home, and referrals to child and adolescent psychiatric clinics during 2014–2018.

Ethics and dissemination: The study design has been approved by the management of the Oulu University Hospital in accordance with the guidelines given by The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. All data are treated and implemented according to national data security laws. Study findings will be disseminated to provincial and municipal partners, collaborative community groups and the research and development community. The LTCE Study databases will guide future regional development action and policies.

Strengths and limitations of this study

- The LTCE Study's protocol is suitable when intervention is implemented annually in real-life municipalities. By creating a regional database for the LTC results, we can sample over 100 000 children and youths. The merit of such large-scale evaluations is high.
- The LTC approach seeks to better link community services provided to families and to assist families in accessing the support they need.
- Adequately measuring individual-level LTC intervention results is difficult, because the framework of strengths and vulnerabilities applies to both the capacity of individuals and their social and physical ecologies.

Introduction

Children's mental health problems disrupt healthy development and are among the leading causes of child and youth disability. [1] Opportunities exist, however, to improve mental capital through different types of intervention: we can try to build the cognitive and emotional resources that influence how an individual is able to experience a high quality of life. Some problems nevertheless extend beyond the individual to family members and communities. Thus, system-wide changes and a settings approach are needed [1, 2]. The emergence of such an approach has been attributed to the Ottawa Charters (WHO, 1986) statement which claims that health is created and lived by people within the settings of their everyday life. More research into system interventions is needed to produce an evidence base to transform child and family services.

Many evidence-based interventions fail to take an ecologic perspective for achieving a population-level impact. Children's problems may develop because of problems within their families or communities, and may include parental mental health problems, food and housing insecurity, or exposure to dangerous neighbourhoods or challenging schools [3]. Intervention may be more effective when directed at the

underlying issues and designed to fit the work flow and staffing of local child and family services [3]. Integration efforts in Finland involve work with school-based and public health services. Health promotion activities are delivered in the context of co-occurring service conditions, and with a focus on both individual and family strengths and vulnerabilities.

A strategic approach to health promotion consist of both managerial and field actions. This enables strong systems in local child and family services, and universal delivery. Service systems are currently often expensive in terms of duplication, inefficiency, and high procurement costs [4]. The challenges to developing child and family services include the fragmentation of services, inter-sector borders, different work cultures, and data transmission difficulties. Furthermore, families have a wide diversity of needs, and varying degrees of access to assistance and advice [5].

In planning the present development programme, we used the following framework to conceptualise the integration of child and family services. Activity integration involves the joint provision of intervention by different sectors of services, and joint training sessions for professionals. At the regional level, policy integration includes the development of a harmonised incentive structure for operationalising actions, and the formation of a new partnership for municipal-based delivery of child and family services. Furthermore, capacity-building strengthens the evaluation of health promotion activities among municipal child and family services.

The present development programme in the Council of Oulu Region is based on elements of brief psycho-educational discussions with parents (Let's Talk about Children, LTC) [5]. LTC was developed for the Effective Family Program, which provided methods for health and social services to support families and children of mentally ill parents. LTC has earlier been tested in mental health clinics to fit the real-life settings of multi-professional child and family services [5-7]. While the LTC development work was initiated in psychiatric services, the present programme will extend the LTC approach to all municipal child and family services.

According to Finnish school health promotion study, most children are happy with their lives. Not all of secondary school-aged children, however, get the best possible start in life: almost 10% of children live in jobless households, 4% see their parents drunk on a weekly basis, 7% report being bullied weekly at school, and 8% have no close friends [8]. In Finland, 6% of children aged 0-17 are subject to a child welfare notification, 5% take part of a child welfare intervention, and 1% have placements outside the home.

The objective of this paper is to describe the protocol of a quasi-experimental ecologic study with a municipal group and multiple time-series design. We will evaluate the effectiveness of a community level intervention across all public child and family services in 30 municipalities in the Council of Oulu Region to promote the socio-emotional well-being of children. The intervention will identify children's needs and provide them with support in a broad spectrum of arenas in which it may be effective. The intervention is expected to produce positive aspects of child development and is impacted through changes to the children's nearest social and physical ecologies. We intend to assess the associations between change in annual coverage of LTC actions and change in different outcome measures among different age groups residing in both urban and rural municipalities. The intervention is expected to improve children's well-being after each municipality implements the LTC activities in all child and family services. We also anticipated changes in incidents of emergency placement or taking a child into care, and in incidents of new referrals to child or adolescent psychiatric units.

Methods and analysis

Design

The present study is an ongoing quasi-experimental ecologic study, which is conducted in a naturalistic setting of public child and family services in the Council of Oulu Region, Finland. The study focuses on the population under the age of 18. We assess the ecologic association between the average LTC intervention activity and the aggregated measurement of the rate of adverse incidents among multiple groups of children. The data sources used involve observations of multiple groups based on place and time (Figure 1). The evaluation consists of data collection at five time points (baseline and four other time points).

The rollout of intervention across municipalities is assigned without using randomization. In each intervention area, the selection and timing is based on the agreement between the municipal town manager and the Council of Oulu Region.

Insert Figure 1 here

Since 2012, LTC services have been applied in some municipalities. The training of service suppliers in LTC intervention was first carried out in the town of Raahe. During the study, the LTC intervention will gradually be conducted in up to 30 municipalities (see participants below), and its activities will branch out year by year (Figure 2). The intervention will be fully implemented by the end of the study, and all municipalities will be involved.

Insert Figure 2 in here

Participants

The "Change now. Let's talk about the children in the Council of Oulu Region" programme is co-ordinated by the Northern Ostrobothnia Hospital District. The programme was planned at both regional and local levels within regional offices, local public sector offices, non-governmental organisations, and other regional partners. The programme co-ordinators guide the activities at the local level. At this local level, the implementers, including municipal employees and relevant community-based partners are all integrated. Interventions are carried out during early childhood education in primary schools, in secondary schools, and in all health and social services.

The evaluation study is conducted by the Oulu University Hospital, in close liaison with the University of Oulu and the University of Lapland. The Oulu University Hospital received circa 250 000 € funding for the implementation of LTC services from member municipalities of the Northern Ostrobothnia Hospital District and the Council of Oulu Region (European Regional Development Fund). The hospital district consists of 30 distinct municipalities, of which 3 are urban (Kempele, Oulu and Raahe), 5 are rural close to urban areas (Ii,

Liminka, Lumijoki, Siikajoki and Tyrnävä), 10 are core rural (Haapajärvi, Haapavesi, Kalajoki, Muhos, Nivala, Oulainen, Pyhäjoki, Reisjärvi, Sievi and Ylivieska) and 12 are sparsely populated rural (Alavieska, Hailuoto, Kuusamo, Kärsämäki, Merijärvi, Pudasjärvi, Pyhäjärvi, Pyhäntä, Siikalatva, Taivalkoski, Utajärvi and Vaala). The classification of municipalities will be described further in the context of statistical analyses.

Multiple children groups by citizenship

The complete numbers of children and young people are retrieved from the Population Statistics (Statistics Finland) and are sorted by the municipalities of the Council of Oulu Region. Population data by age group reveal the municipality's permanent resident population in each age group on the last day of the year. The multiple age groups evaluated in the study are 0–6-year-olds, and 7–16-year-olds. Table 1A presents a description of the groups and measures used in data collection.

Table 1. Description of study population and measures used in data collection, 2013.

Area	Population*		Child welfare actions				Psychiatric referrals	
			Notification**	Intervention***	Placement****	Home help[§]		
	aged 0–9 n	10–19 n	aged 0–17 n	0–17 n	0–17 n		0–17 n	13–22 n
Alavieska	348	406	65	48	7	0		5
Haapajärvi	1020	1106	132	190	21	20	8	12
Haapavesi	976	1065	77	108	18	0	3	4
Hailuoto	80	87	19	11	0	0		1
Ii	1584	1311	161	209	7	19	11	5
Kalajoki	1647	1605	125	66	21	8	1	1
Kempele	2852	2496	428	264	32	54	19	9
Kuusamo	1649	1887	137	233	49	89	3	7
Kärsämäki	323	367	47	97	12	9	2	1
Liminka	2351	1708	248	120	10	31	11	7
Lumijoki	435	324	46	126		14		3
Merijärvi	178	179	13	8	0	0		
Muhos	1550	1361	165	127	20	52	8	9
Nivala	1803	1606	284	275	34	0	6	6
Oulainen	999	1078	164	106	19	0	6	3
Oulu	26476	23337	4822	3719	672	860	110	105
Pudasjärvi	890	1036	103	121	21	0	4	3
Pyhäjoki	408	406	64	36		6	7	
Pyhäjärvi	574	587	107	123	16	6	3	2
Pyhäntä	211	234	25	7		0		4
Raahe	3354	3183	570	321	80	60	19	12
Reisjärvi	380	404	76	59	8	9		
Sievi	952	911	122	132	13	0	1	3
Siikajoki	848	790	136	83	20	10	8	3

Siikalatva	613	677	62	74	10	0	4	5
Taivalkoski	438	552	46	40	17	0	2	3
Tyrnävä	1562	1076	156	139	9	1	3	6
Utajärvi	319	360	48	82	10	0	5	2
Vaala	254	365	117	59	17	22	7	6
Ylivieska	2182	1869	290	326	39	0	7	12
Total	***57256***	***52373***	***8855***	***7309***	***1182***	***1270***	***258***	***239***

* Population by age group, year-end total
** Number of child welfare notifications
*** Number of child welfare interventions and in community care
**** Number of placements outside the home.
ˢ Home help, recipient families with children

Intervention across all the municipal child and family services

The primary objective of the LTC intervention is to improve socio-emotional well-being among children and adolescents. We aim to promote health by making changes to modifiable risk conditions, and supportive changes through attributes that help children grow and develop successfully. At a system level, the LTC development programme also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of this system to maintain LTC activities, and to catching risk conditions before they get worse. A regional steering committee has been established by the Council of Oulu Region. The committee functions as ensuring coordinated actions and development. The committee will deliberate on regional establishment issues and challenges, engage with stakeholders, review and comment on progress made and exchange of experience between the municipalities. The steering committee will provide resources and support for initiating the local activities, ultimately aiming to make LTC discussions and network meetings self-sustaining over time.

At the local level, the intervention is implemented and co-ordinated by a Local Management Team (LMT). The LMT includes managers of early childhood education, primary schools, health services, and social services. Each LMT is responsible for implementing the LTC approach in the child and family services of the municipality. Each must have a different LMT due to the large number of service units (kindergartens,

schools, health and social care centres), and because the units are spread across the whole county. No one LMT is big enough to cover the whole county.

Each municipality has a four-month "municipal engagement phase" prior to the local trainers' training (Figure 2). During this phase, the LMT engages in the LTC intervention activities with the elected member structures, schools and other units. The trainers are then trained in LTC discussion and network meetings. These training sessions are subsidised by programme resources and are free for the municipalities and for the participants. The LMT co-ordinates trainers' training by finding participants having an avid interest in the subject. The LMT also advertises the LTC activities in local media (e.g., newspapers, posters and leaflets). The local trainers then deliver LTC discussion training sessions to their colleagues in the municipal child and family services units.

Each LMT is given strategic support, as well as a clear framework and timescales for the assessment of the local activities and outcomes. The Oulu University Hospital annually co-ordinates the intervention activities led by the LMT, that consists of local managers. Furthermore, appropriate specialist support and mentoring is provided to help the LMT in collecting data and sustaining the local units in their LTC intervention activities. All the LMTs are responsible for the implementation and continuity of the universal LTC activities with parents.

All parents are offered the opportunity to take part in an LTC discussion and are shown the structure of the discussion themes. If they agree, they make an appointment with the professional. At the family level, the LTC practices includes universal LTC discussion for parents and an LTC network meeting for parents who need support.

LTC practices for children's health promotion

LTC discussion

This parent-focused method has been described earlier [9]. Briefly, the aim of the LTC discussion is to help parents recognise their children's strengths and vulnerabilities, and to inform them of ways in which to support their children, despite possible family problems. The LTC discussion consists of one or two sessions

with the parent or both parents. The child's own teacher, nurse or social worker is also present. The LTC manuals are available in Finnish on the internet for use in early childhood education, primary school, secondary school and all health and social services [9].

When parents bring up a problem that the family is currently facing; for example, poverty, unemployment and housing problems, a further network meeting is offered. If the parents accept, the meeting is organised with the partners that are expected to be able to help the family.

LTC network meeting

The LTC network meeting is designed to respond to the different needs of the family on an ecologic base. Depending on these needs, service representatives in addition to the family's own network are invited to the meeting. The aim of the LTC network meeting is to activate all participants to provide the child and the family with support. The meeting offers a joint action forum for the aid and social support required [10].

LTC activities must be measured in order to be implemented. In each municipality, the intervention includes measures on the operational data of LTC discussions and LTC network meetings. From 2015 onwards, aggregated counts of LTC discussions and network meetings have been obtained from each municipality of the Council of Oulu Region. We use a time-series design to compare different LTC-intervention intensity among the age groups of 0–6 years and 7–16 years.

Outcome measurement

We assess children's adverse outcomes on the basis of geographically and temporally defined populations. Outcome measurements are averaged for the populations in each geographical or temporal unit and then compared using standard statistical methods. The primary analysis compares the proportion of children referred to child welfare services through LTC activities of different intensities. The proportion of children referred to psychiatric clinics is also analysed. Secondary outcomes are the proportion of children who report being in moderate or poor health, experience inadequate parenting, have moderate or severe

anxiety, have difficulties talking to their parents, and feel that teachers are not interested in how they are doing.

Data sources

The follow-up of child and family service development includes items on commitment made by local organisations, local management groups, trainers' training and local training of personnel. Each municipality has a contract in to the LTC approach together with the Council of Oulu Region. Programme maintenance and sustainability includes items on how LTC activities are adopted into the regular activity of all child and family services, and how LTC activities are maintained by local organisations. Problem-solving ability includes how to tackle children's health issues as an activity of its own, and how participants work together to plan actions.

Online questionnaires are sent out by e-mail to each local management group once a year, in January, and the respondents fill in the questionnaire themselves. Additional requests are made until data from each participating municipality are received. Then the intervention phase (control phase, training and implementing phase, and constant actions) is recorded for each municipality at baseline and after each of the four following intervention periods, i.e. calendar year.

In Finland, municipalities are obliged to collect and report child welfare data. Each year, they receive a data request form that they must fill in within a specified time. They are instructed to log onto the Lasu-Netti website and check the provided list of current placements, record any changes to placements, and record data on support interventions in community care. The child welfare data are retrieved in electronic form and updated on the national database. Child welfare statistics have been compiled and processed by the National Institute for Health and Welfare since 1991.

In Finland, the nationwide School Health Promotion study monitors the health and well-being of Finnish adolescents. The School Health Promotion study is carried out every other year in March/April. Since 1996,

the study has surveyed 8th and 9th graders (ages 14-15) in comprehensive schools. For example, the questionnaire includes the measures that are shown in Table 2.

Table 2 In 2013, the School Health Promotion study monitored the health of 8th and 9th graders in comprehensive schools in the municipalities of the Council of Oulu Region. The number represents the proportion of children who experienced the problem in relation to all those who responded to the survey (Sotkanet, Institute for Health and Welfare).

Measure	2013 %
Inadequate parenting (ind. 284)	17.6
In moderate or poor health (ind. 286)	16.2
Moderate or severe anxiety (ind. 328)	11.1
Difficulties talking to parents (ind. 329)	8.6
Teachers not interested in how pupil is doing (ind. 355)	58.0

The data are gathered via an anonymous and voluntary classroom-administered questionnaire. Although the questionnaire is continuously being developed, most of the questions have remained the same for almost 20 years, to maintain comparability.

Child welfare notifications

The measures provides the numbers of child welfare notifications filed during a calendar year. The notification is filed in the municipal unit responsible for civic social services. According to the Finnish Child Welfare Act, a child welfare notification is when someone observes or reports circumstances relating to the care and upbringing of a child that may require an assessment regarding the need for child welfare measures. This can be made by phone, in writing or by visiting the municipal office in person.

Child welfare interventions in community care

The measures also depict the numbers of children receiving support via a community-based child welfare intervention during a calendar year: the community care support intervention comprises support for a child's accommodation, livelihood, school attendance, and hobbies. The measure also includes children receiving community care support before a placement. Before a child is placed outside the home, any opportunities for the child to live with relatives or other people they are close to must be investigated.

Placements outside the home

Finally, the measures show the numbers of children who have been placed outside the home during a calendar year. They include counts of children being placed outside the home through a child welfare intervention in community care, counts of emergency placements, counts of children taken into care involuntarily, and counts of children who receive after-care outside the home. The causes behind these placements may be related to parents or to the children themselves. Substance abuse is often an underlying factor.

Referrals to child and adolescent psychiatric clinics

Oulu University Hospital provides treatment for children in the Northern Ostrobothnia Hospital District and in northern Finland. Hospital referrals are made with the intention that the patient will be assessed and treated before responsibility is transferred back to the referring health professional or general practitioner. Any hospital that receives referrals will need to obtain information on these patients.

LTC discussion and network meeting data

In each local unit, each professional who is offering an LTC discussion keeps a record of the LTC discussions held. Furthermore, each professional who convenes an LTC network meeting also keeps a record. After each calendar year, all the LMTs that have passed the community engagement phase are contacted by email and online survey form. The aggregated counts of LTC services are reported for each municipal child and family service sector. Data collection is co-ordinated by the office of the Primary Health Care Unit of the Northern Ostorobothnia Hospital District.

Effect-measure modification

Home help rate, recipient families with children is the measure of the annual rate of families with children that receive home help from municipal welfare services. The denominator is the number of households with at least one person aged under 18 in the same year (Statistics Finland). Home help includes, for example, assistance with activities related to personal care, child care and other daily family activities. The data cover the services funded by municipalities, that is, services that the municipality has produced or paid for. Services funded by the clients themselves are not included.

LTC intervention rate is the measure of the annual rate of children who attend an LTC discussion in municipal child and family services. The denominator is the number of children in the same year.

Classification of municipalities. The areal division by Finnish Area Research [11] reveals the differences in socioeconomic and endogenous development factors of the municipalities. It divides municipalities into four categories: urban areas (cities and towns), rural municipalities close to urban areas, core rural municipalities, and sparsely populated rural municipalities. ***Urban areas*** are those that form centres of high economic importance. In ***rural municipalities close to urban*** *areas*, residents have the option of working in nearby towns and cities with highly diverse businesses. These economically integrated rural municipalities have a high level of welfare. ***Core rural municipalities*** are situated close to several medium-to-large centres, and most of the villages they contain are economically viable. ***Sparsely populated rural***

municipalities are characterised by long distances from municipal centres and have rapidly declining populations. These municipalities face the threat of a cycle of poor development: not enough new jobs are available to replace the traditional jobs that are disappearing, young people move away, services disappear, and the capacity of municipalities for economic management is low.

Data analysis

Each calendar year, aggregated counts of child welfare notifications, child welfare and community care interventions, and child placements outside the home are described for each municipality. Incidence rates and proportions for each event will then be computed by dividing the annual counts by the year-end total population. Incidence rates and proportions of referrals to child psychiatric clinics are also described each calendar year for each municipality. The LTC intervention data are calculated by dividing the number of LTC discussions by the population eligible for the intervention. Then, for each municipality, LTC intervention data collected across all study periods are classified into four categories according to the phase of the LTC implementation: control period, training in LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions.

During 2014–2018, we will follow 500 000 person-years across the age-group of 0–17 years. To summarise the relationship between LTC services and outcome variables, we use descriptive contingency tables. A categorised LTC variable is tabulated for each outcome variable. The table is created to display data for any outcome measure (number of events and incidence rate) and subcategories of LTC services (control period, training in LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions). Most LTC services are rendered among families with school-aged children. Hence, similar analyses will be performed that separate data into subsamples according to age. Stratified analyses will include age groups of 0–6 and 7–17 years.

There are background differences between municipalities. To control for potential confounding, we use we use adjustment for municipal categories. For any given outcome, regression analysis involves the group-

specific incidence rates and the group-specific coverage data of LTC discussions. We apply a log-linear model in the analysis of incidence rate-ratio estimation. The results of statistical analyses are presented as incidence rate ratios with 90% confidence intervals and *p*-values.

Ethics and dissemination

The study design has been approved by the management of Oulu University Hospital in accordance with the guidelines of The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. The Regional Ethics committee concluded that this study does not require ethics approval.

The two rationales behind the present study design are: individual-level LTC intervention is difficult to measure in real life, because the framework of strengths and vulnerabilities applies to both the capacity of individuals and their social and physical ecologies. Moreover, in the Council of Oulu Region, all the municipal authorities autonomously make decisions on the implementation of LTC interventions. All data are treated and implemented according to national data security laws.

All parents are offered the opportunity to take part in an LTC discussion and are shown the structure of the discussion themes. If they agree, they make an appointment with the professional. In natural settings of child and family services, written consent is not necessary.

This paper outlines the LTC activities of the Council of Oulu Region's evaluation study, its design and data collection, and details on the implementation of the intervention. The LTC evaluation study uses a quasi-experimental trial design to evaluate the effectiveness of a community-level intervention that aims to improve children's well-being. This design is suitable in cases when the intervention cannot be delivered to all intervention areas at the same time.

The strengths of the study include the large number of participating municipalities and the multiple data collection stages. An LTC intervention in local child and family services may reduce the need for highly

specialised child protection and child psychiatric services in northern Finland. The results from the study will contribute to the limited research available on the effectiveness of promoting children's well-being via an intervention programme that uses the child and family services approach.

This pragmatic evaluation of a community-led intervention in a real-life multi-professional setting is expected to provide information on adapting evidence-based methods for diverse municipalities. Child and family services are often renewed and directed in such ways that leave little, if any, resources for programme evaluation and outcome monitoring. In this study, independent regional investigators work together with local professionals to assess, in real-life settings, the association between the change in the local LTC intervention rate and the change in ecologic measures of children's health.

The LTC evaluation study in the Council of Oulu Region aims to expand our knowledge on the effectiveness of promoting children's health via an intervention programme that uses a multi-sectorial approach. At the same time, it improves co-operation between researchers and practitioners. The results can be useful for both the researchers and the managers leading the local reform of public child and family services. If the LTC intervention proves to be effective, the intervention programme can be distributed throughout Finland, as well as in other high-income countries.

List of abbreviations

LTCE = Let's Talk about Children Evaluation

LTC = Let's Talk about Children, a brief psychoeducational discussion with parents

LMT = Local Management Team

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Authors' contributions

VK and JJ obtained funding for the study. JJ further developed the intervention. VK designed the ecologic part of the study. HE and AP contributed to the study design. VK wrote this paper. All authors drafted and approved the final version of the manuscript.

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Competing interests: The authors declare that they have no competing interests.

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Figure legends

Figure 1 Design of present study. Blocks of municipalities represent groups of intervention areas. Each time point (T0, T1, T2, T3, or T4) represents a data collection point. Each unit (control or intervention) represents one time period for one block of municipalities.

Figure 2 Data collection timeline for the Let's talk about the children evaluation study.

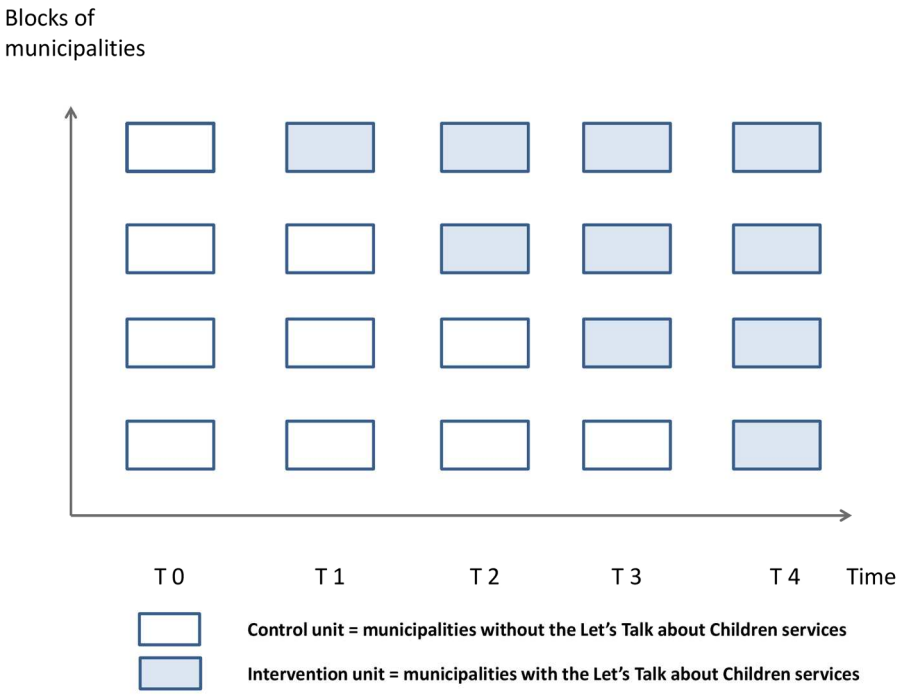

Figure 1 Design of the present study. Blocks of municipalities represent group of intervention areas. Each time period (T0, T1, T2, T3, or T4) represents a data collection point. Each unit (control or intervention) represents one time period of one block of municipalities.

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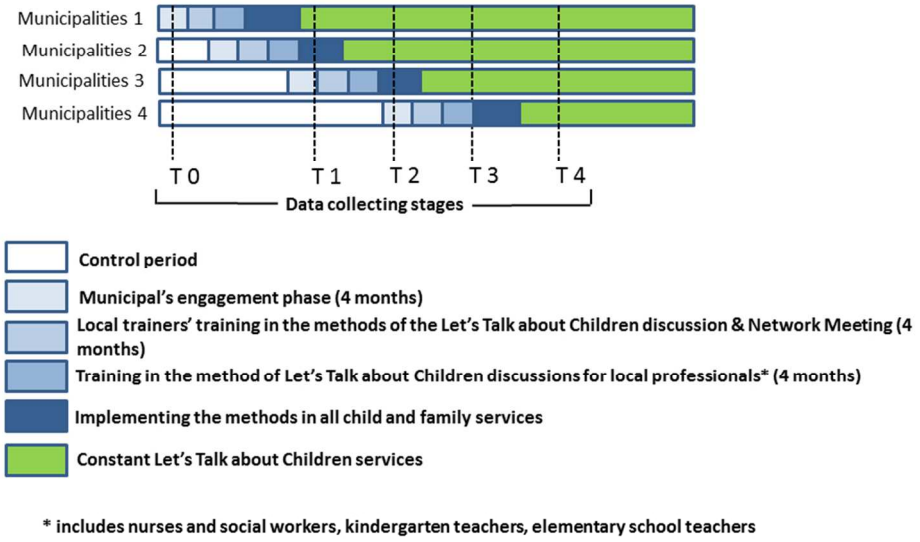

Figure 2. Data collection timeline for the Let's talk about the children evaluation study.

254x190mm (96 x 96 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-10
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	n/a
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*12-14*
Bias	9	Describe any efforts to address potential sources of bias	14-15
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	15-16
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	

		(*e*) Describe any sensitivity analyses	Page no results are shown
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Ethics and dissemination			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	n/a
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18-19

BMJ Open

Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design

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Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design

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Abstract

Introduction: Making change towards child and family-based and coordinated services is critical to improve quality, outcomes and value. The Let's Talk about Children (LTC) approach, which consists of brief psycho-educational discussions with parents of kindergarten- and school-aged children, has been launched as a municipality-specific program in the Council of Oulu Region. The aim of this paper is to present a protocol of an ecologic study evaluating the group-specific effects of an intervention about LTC activities in a geographically defined population. The program is designed to promote children's socio-emotional well-being.

Methods and analysis: A quasi-experimental ecologic study protocol is implemented to evaluate whether systematic LTC practices improve children's well-being. A multi-informant setting covers 30 municipalities in northern Finland, and involves all the municipal teachers, social and health care workers. In each municipality a Local Management Team is responsible for implementing the LTC program and collecting the annual data of LTC discussions and network meetings. The outcome data is retrieved from child welfare statistics and hospital registers. The population data, child welfare statistics and referrals to hospitals was retrieved at baseline (2014), and will be retrieved annually. Furthermore, the annual data of LTC discussions and network meetings will be collected of the years 2015-2018.

Ethics and dissemination: The study design has been approved by the management of the Oulu University Hospital in accordance with the guidelines given by The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. All data are treated and implemented according to national data security laws. Study findings will be disseminated to provincial and municipal partners, collaborative community groups and the research and development community. The LTCE Study databases will guide future regional development action and policies.

Strengths and limitations of this study

- The LTCE Study's protocol is suitable when intervention is implemented annually in real-life municipalities. By creating a regional database for the LTC results, we can sample over 100 000 children and youths. The merit of such large-scale evaluations is high.
- The LTC approach seeks to better link community services provided to families and to assist families in accessing the support they need.
- Adequately measuring individual-level LTC intervention results is difficult, because the framework of strengths and vulnerabilities applies to both the capacity of individuals and their social and physical ecologies.

Introduction

Children's mental health problems disrupt healthy development and are among the leading causes of child and youth disability. [1] Opportunities exist, however, to improve mental capital through interventions: we can try to build the cognitive and emotional resources that influence how an individual is able to experience a high quality of life. Some problems nevertheless extend beyond the individual to family members and communities. Thus, system-wide changes and a settings approach are needed [1, 2]. The emergence of such an approach has been attributed to the Ottawa Charters (WHO, 1986) statement which claims that health is created and lived by people within the settings of their everyday life. More research into system interventions is needed to produce an evidence base to transform child and family services.

Many evidence-based interventions fail to take an ecologic perspective for achieving a population-level impact. Children's problems may develop because of problems within their families or communities, and may include parental mental health problems, food and housing insecurity, or exposure to dangerous neighbourhoods or challenging schools [3]. Intervention may be more effective when directed at the underlying issues and designed to fit the work flow and staffing of local child and family services [3].

Integration efforts in Finland involve work with school-based and public health services. Health promotion activities are delivered in the context of co-occurring service conditions, and with a focus on both individual and family strengths and vulnerabilities.

A strategic approach to health promotion consist of both managerial and operational actions. This enables strong systems in local child and family services, and universal delivery. Service systems are currently often expensive in terms of duplication, inefficiency, and high procurement costs [4]. The challenges to developing child and family services include the fragmentation of services, inter-sector borders, different work cultures, and data transmission difficulties. Furthermore, families have a wide diversity of needs, and varying degrees of access to assistance and advice [5].

In planning the present development programme, we used the following framework to conceptualise the integration of child and family services. Activity integration involves the joint provision of intervention by different sectors of services, and joint training sessions for professionals. At the regional level, policy integration includes the development of a harmonised incentive structure for operationalising actions, and the formation of a new partnership for municipal-based delivery of child and family services. Furthermore, capacity-building strengthens the evaluation of health promotion activities among municipal child and family services.

The present development programme in the Council of Oulu Region is based on elements of brief psycho-educational discussions with parents (Let's Talk about Children, LTC) [5]. LTC was developed for the Effective Family Program, which provided methods for health and social services to support families and children of mentally ill parents. LTC has earlier been tested in mental health clinics to fit the real-life settings of multi-professional child and family services [5-7]. While the LTC development work was initiated in psychiatric services, the present programme will extend the LTC approach to all municipal child and family services.

According to Finnish school health promotion study, most children are happy with their lives [8]. Not all of secondary school-aged children, however, get the best possible start in life: almost 10% of children live in

jobless households, 4% see their parents drunk on a weekly basis, 7% report being bullied weekly at school, and 8% have no close friends [8]. In Finland, 6% of children aged 0-17 are subject to a child welfare notification, 5% take part of a child welfare intervention, and 1% have placements outside the home.

The objective of this paper is to describe the protocol of a quasi-experimental ecologic study with a municipal group and multiple time-series design. We will evaluate the effectiveness of a community level intervention across all public child and family services in 30 municipalities in the Council of Oulu Region to promote the socio-emotional well-being of children. The intervention will identify children's needs and provide them with support in a broad spectrum of arenas in which it may be effective. The intervention is expected to produce positive aspects of child development and is impacted through changes to the children's nearest social and physical ecologies. We intend to assess the associations between change in annual coverage of LTC actions and change in different outcome measures among different age groups residing in both urban and rural municipalities. The intervention is expected to improve children's well-being after each municipality implements the LTC activities in all child and family services. We also anticipated changes in incidents of emergency placement or taking a child into care, and in incidents of new referrals to child or adolescent psychiatric units.

Methods and analysis

Design

The present study is an ongoing quasi-experimental ecologic study, which is conducted in a naturalistic setting of public child and family services in the Council of Oulu Region, Finland. The study focuses on the population under the age of 18. We assess the ecologic association between the average LTC intervention activity and the aggregated measurement of the rate of adverse incidents among multiple groups of children. The data sources used involve observations of multiple groups based on place and time (Figure 1). The evaluation consists of data collection at five time points (baseline and four other time points).

The rollout of intervention across municipalities is assigned without using randomization. In each intervention area, the selection and timing is based on the agreement between the municipal town manager and the Council of Oulu Region.

Insert Figure 1 here

Since 2012, LTC services have been applied in some municipalities. The training of service suppliers in LTC intervention was first carried out in the town of Raahe. During the study, the LTC intervention will gradually be conducted in up to 30 municipalities (see participants below), and its activities will branch out year by year (Figure 2). The intervention will be fully implemented by the end of the study, and all municipalities will be involved.

Insert Figure 2 in here

Participants

The "Change now. Let's talk about the children in the Council of Oulu Region" programme is co-ordinated by the Northern Ostrobothnia Hospital District. The programme was planned at both regional and local levels within regional offices, local public sector offices, non-governmental organisations, and other regional partners. The programme co-ordinators guide the activities at the local level. At this local level, the implementers, including municipal employees and relevant community-based partners are all integrated. Interventions are carried out during early childhood education in primary schools, in secondary schools, and in all health and social services.

The evaluation study is conducted by the Oulu University Hospital, in close liaison with the University of Oulu and the University of Lapland. The Oulu University Hospital received circa 250 000 € funding for the implementation of LTC services from member municipalities of the Northern Ostrobothnia Hospital District and the Council of Oulu Region (European Regional Development Fund). The hospital district consists of 30 distinct municipalities, of which 3 are urban (Kempele, Oulu and Raahe), 5 are rural close to urban areas (Ii,

Liminka, Lumijoki, Siikajoki and Tyrnävä), 10 are core rural (Haapajärvi, Haapavesi, Kalajoki, Muhos, Nivala, Oulainen, Pyhäjoki, Reisjärvi, Sievi and Ylivieska) and 12 are sparsely populated rural (Alavieska, Hailuoto, Kuusamo, Kärsämäki, Merijärvi, Pudasjärvi, Pyhäjärvi, Pyhäntä, Siikalatva, Taivalkoski, Utajärvi and Vaala). The classification of municipalities will be described further in the context of statistical analyses.

Multiple children groups by citizenship

The complete numbers of children and young people are retrieved from the Population Statistics (Statistics Finland) and are sorted by the municipalities of the Council of Oulu Region. Population data by age group reveal the municipality's permanent resident population in each age group on the last day of the year. The multiple age groups evaluated in the study are 0–6-year-olds, and 7–16-year-olds. Table 1 presents a description of the groups and measures used in data collection.

Table 1. Description of study population and measures used in data collection, 2013.

Area	Population*		Child welfare actions				Psychiatric referrals	
			Notification**	Intervention***	Placement****	Home help[ŝ]		
	aged 0–9 n	10–19 n	aged 0–17 n	0–17 n	0–17 n		0–17 n	13–22 n
Alavieska	348	406	65	48	7	0		5
Haapajärvi	1020	1106	132	190	21	20	8	12
Haapavesi	976	1065	77	108	18	0	3	4
Hailuoto	80	87	19	11	0	0		1
Ii	1584	1311	161	209	7	19	11	5
Kalajoki	1647	1605	125	66	21	8	1	1
Kempele	2852	2496	428	264	32	54	19	9
Kuusamo	1649	1887	137	233	49	89	3	7
Kärsämäki	323	367	47	97	12	9	2	1
Liminka	2351	1708	248	120	10	31	11	7
Lumijoki	435	324	46	126		14		3
Merijärvi	178	179	13	8	0	0		
Muhos	1550	1361	165	127	20	52	8	9
Nivala	1803	1606	284	275	34	0	6	6
Oulainen	999	1078	164	106	19	0	6	3
Oulu	26476	23337	4822	3719	672	860	110	105
Pudasjärvi	890	1036	103	121	21	0	4	3
Pyhäjoki	408	406	64	36		6	7	
Pyhäjärvi	574	587	107	123	16	6	3	2
Pyhäntä	211	234	25	7		0		4
Raahe	3354	3183	570	321	80	60	19	12
Reisjärvi	380	404	76	59	8	9		
Sievi	952	911	122	132	13	0	1	3
Siikajoki	848	790	136	83	20	10	8	3

Siikalatva	613	677	62	74	10	0	4	5
Taivalkoski	438	552	46	40	17	0	2	3
Tyrnävä	1562	1076	156	139	9	1	3	6
Utajärvi	319	360	48	82	10	0	5	2
Vaala	254	365	117	59	17	22	7	6
Ylivieska	2182	1869	290	326	39	0	7	12
Total	***57256***	***52373***	***8855***	***7309***	***1182***	***1270***	***258***	***239***

* Population by age group, year-end total
** Number of child welfare notifications
*** Number of child welfare interventions and in community care
**** Number of placements outside the home.
ˢ Home help, recipient families with children

The study began in January 2014 and will be completed in December 2018. The different stages of data collection regarding both, summaries of observations derived from individuals in groups identified by citizenship (multi-group design) and by time (time-trend design), and data retrieved the national statistics (a Gantt chart shown in Figure 3). Based on data by place and time, the interpretation of estimated effects is enhanced because two types of comparisons are made simultaneously: change over time within age-groups and differences among municipalities with different phase of implementing the LTC activities in all municipal child and family services.

Insert Fig 3 in here

Intervention across all the municipal child and family services

The primary objective of the LTC intervention is to improve socio-emotional well-being among children and adolescents. We aim to promote health by making changes to modifiable risk conditions, and supportive changes through attributes that help children grow and develop successfully. At a system level, the LTC development programme also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of this system to maintain LTC activities, and to catching risk conditions before they get worse. A regional steering committee has been established by the Council of Oulu Region. The committee functions as ensuring coordinated actions and development. The committee

will deliberate on regional establishment issues and challenges, engage with stakeholders, review and comment on progress made and exchange of experience between the municipalities. The steering committee will provide resources and support for initiating the local activities, ultimately aiming to make LTC discussions and network meetings self-sustaining over time.

At the local level, the intervention is implemented and co-ordinated by a Local Management Team (LMT). The LMT includes managers of early childhood education, primary schools, health services, and social services. Each LMT is responsible for implementing the LTC approach in the child and family services of the municipality. Each must have a different LMT due to the large number of service units (kindergartens, schools, health and social care centres), and because the units are spread across the whole county. No one LMT is big enough to cover the whole county.

Each municipality has a four-month "municipal engagement phase" prior to the local trainers' training (Figure 2). During this phase, the LMT engages in the LTC intervention activities with the elected member structures, schools and other units. The trainers are then trained in LTC discussion and network meetings. These training sessions are subsidised by programme resources and are free for the municipalities and for the participants. The LMT co-ordinates trainers' training by finding participants having an avid interest in the subject. The LMT also advertises the LTC activities in local media (e.g., newspapers, posters and leaflets). The local trainers then deliver LTC discussion training sessions to their colleagues in the municipal child and family services units.

Each LMT is given strategic support, as well as a clear framework and timescales for the assessment of the local activities and outcomes. The Oulu University Hospital annually co-ordinates the intervention activities led by the LMT, that consists of local managers. Furthermore, appropriate specialist support and mentoring is provided to help the LMT in collecting data and sustaining the local units in their LTC intervention activities. All the LMTs are responsible for the implementation and continuity of the universal LTC activities with parents.

All parents are offered the opportunity to take part in an LTC discussion and are shown the structure of the discussion themes. If they agree, they make an appointment with the professional. At the family level, the LTC practices includes universal LTC discussion for parents and an LTC network meeting for parents who need support.

LTC practices for children's health promotion

LTC discussion

This parent-focused method has been described earlier [9]. Briefly, the aim of the LTC discussion is to help parents recognise their children's strengths and vulnerabilities, and to inform them of ways in which to support their children, despite possible family problems. The LTC discussion consists of one or two sessions with the parent or both parents. The child's own teacher, nurse or social worker is also present. The LTC manuals are available in Finnish on the internet for use in early childhood education, primary school, secondary school and all health and social services [9].

When parents bring up a problem that the family is currently facing; for example, poverty, unemployment and housing problems, a further network meeting is offered. If the parents accept, the meeting is organised with the partners that are expected to be able to help the family.

LTC network meeting

The LTC network meeting is designed to respond to the different needs of the family on an ecologic base. Depending on these needs, service representatives in addition to the family's own network are invited to the meeting. The aim of the LTC network meeting is to activate all participants to provide the child and the family with support. The meeting offers a joint action forum for the aid and social support required [10].

LTC activities must be measured in order to be implemented. In each municipality, the intervention includes measures on the operational data of LTC discussions and LTC network meetings. From 2015 onwards, aggregated counts of LTC discussions and network meetings have been obtained from each municipality of the Council of Oulu Region. We use a time-series design to compare different LTC-intervention intensity among the age groups of 0–6 years and 7–16 years.

Outcome measurement

We assess children's adverse outcomes on the basis of geographically and temporally defined populations. Outcome measurements are averaged for the populations in each geographical or temporal unit and then compared using standard statistical methods. The primary analysis compares the proportion of children referred to child welfare services through LTC activities of different intensities. The proportion of children referred to psychiatric clinics is also analysed. Secondary outcomes are the proportion of children who report being in moderate or poor health, experience inadequate parenting, have moderate or severe anxiety, have difficulties talking to their parents, and feel that teachers are not interested in how they are doing.

Data sources

The follow-up of child and family service development includes items on commitment made by local organisations, local management groups, trainers' training and local training of personnel. Each municipality has a contract in to the LTC approach together with the Council of Oulu Region. Programme maintenance and sustainability includes items on how LTC activities are adopted into the regular activity of all child and family services, and how LTC activities are maintained by local organisations. Problem-solving ability includes how to tackle children's health issues as an activity of its own, and how participants work together to plan actions.

Online questionnaires are sent out by e-mail to each local management group once a year, in January, and the respondents fill in the questionnaire themselves. Additional requests are made until data from each participating municipality are received. Then the intervention phase (control phase, training and implementing phase, and constant actions) is recorded for each municipality at baseline and after each of the four following intervention periods, i.e. calendar year.

In Finland, municipalities are obliged to collect and report child welfare data. Each year, they receive a data request form that they must fill in within a specified time. They are instructed to log onto the Lasu-Netti website and check the provided list of current placements, record any changes to placements, and record data on support interventions in community care. The child welfare data are retrieved in electronic form and updated on the national database. Child welfare statistics have been compiled and processed by the National Institute for Health and Welfare since 1991.

In Finland, the nationwide School Health Promotion study monitors the health and well-being of Finnish adolescents. The School Health Promotion study is carried out every other year in March/April. Since 1996, the study has surveyed 8th and 9th graders (ages 14-15) in comprehensive schools. For example, the questionnaire includes the measures that are shown in Table 2.

Table 2 In 2013, the School Health Promotion study monitored the health of 8th and 9th graders in comprehensive schools in the municipalities of the Council of Oulu Region. The number represents the proportion of children who experienced the problem in relation to all those who responded to the survey (Sotkanet, Institute for Health and Welfare).

Measure	2013 %
Inadequate parenting (ind. 284)	17.6
In moderate or poor health (ind. 286)	16.2
Moderate or severe anxiety (ind. 328)	11.1
Difficulties talking to parents (ind. 329)	8.6
Teachers not interested in how pupil is doing (ind. 355)	58.0

The data are gathered via an anonymous and voluntary classroom-administered questionnaire. Although the questionnaire is continuously being developed, most of the questions have remained the same for almost 20 years, to maintain comparability.

Child welfare notifications

The measures provides the numbers of child welfare notifications filed during a calendar year. The notification is filed in the municipal unit responsible for civic social services. According to the Finnish Child Welfare Act, a child welfare notification is when someone observes or reports circumstances relating to the care and upbringing of a child that may require an assessment regarding the need for child welfare measures. This can be made by phone, in writing or by visiting the municipal office in person.

Child welfare interventions in community care

The measures also depict the numbers of children receiving support via a community-based child welfare intervention during a calendar year: the community care support intervention comprises support for a child's accommodation, livelihood, school attendance, and hobbies. The measure also includes children receiving community care support before a placement. Before a child is placed outside the home, any opportunities for the child to live with relatives or other people they are close to must be investigated.

Placements outside the home

Finally, the measures show the numbers of children who have been placed outside the home during a calendar year. They include counts of children being placed outside the home through a child welfare intervention in community care, counts of emergency placements, counts of children taken into care involuntarily, and counts of children who receive after-care outside the home. The causes behind these placements may be related to parents or to the children themselves. Substance abuse is often an underlying factor.

Referrals to child and adolescent psychiatric clinics

Oulu University Hospital provides treatment for children in the Northern Ostrobothnia Hospital District and in northern Finland. Hospital referrals are made with the intention that the patient will be assessed and treated before responsibility is transferred back to the referring health professional or general practitioner. Any hospital that receives referrals will need to obtain information on these patients.

LTC discussion and network meeting data

In each local unit, each professional who is offering an LTC discussion keeps a record of the LTC discussions held. Furthermore, each professional who convenes an LTC network meeting also keeps a record. After each calendar year, all the LMTs that have passed the community engagement phase are contacted by email and online survey form. The aggregated counts of LTC services are reported for each municipal child and family service sector. Data collection is co-ordinated by the office of the Primary Health Care Unit of the Northern Ostorobothnia Hospital District.

Effect-measure modification

Home help rate, recipient families with children is the measure of the annual rate of families with children that receive home help from municipal welfare services. The denominator is the number of households with at least one person aged under 18 in the same year (Statistics Finland). Home help includes, for example, assistance with activities related to personal care, child care and other daily family activities. The data cover the services funded by municipalities, that is, services that the municipality has produced or paid for. Services funded by the clients themselves are not included.

LTC intervention rate is the measure of the annual rate of children who attend an LTC discussion in municipal child and family services. The denominator is the number of children in the same year.

Classification of municipalities. The areal division by Finnish Area Research [11] reveals the differences in socioeconomic and endogenous development factors of the municipalities. It divides municipalities into four categories: urban areas (cities and towns), rural municipalities close to urban areas, core rural municipalities, and sparsely populated rural municipalities. ***Urban areas*** are those that form centres of high economic importance. In ***rural municipalities close to urban*** *areas*, residents have the option of working in nearby towns and cities with highly diverse businesses. These economically integrated rural municipalities have a high level of welfare. ***Core rural municipalities*** are situated close to several medium-to-large centres, and most of the villages they contain are economically viable. ***Sparsely populated rural***

municipalities are characterised by long distances from municipal centres and have rapidly declining populations. These municipalities face the threat of a cycle of poor development: not enough new jobs are available to replace the traditional jobs that are disappearing, young people move away, services disappear, and the capacity of municipalities for economic management is low.

Data analysis

Each calendar year, aggregated counts of child welfare notifications, child welfare and community care interventions, and child placements outside the home are described for each municipality. Incidence rates and proportions for each event will then be computed by dividing the annual counts by the year-end total population. Incidence rates and proportions of referrals to child psychiatric clinics are also described each calendar year for each municipality. The LTC intervention data are calculated by dividing the number of LTC discussions by the population eligible for the intervention. Then, for each municipality, LTC intervention data collected across all study periods are classified into four categories according to the phase of the LTC implementation: control period, training in LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions.

During 2014–2018, we will follow 500 000 person-years across the age-group of 0–17 years. To summarise the relationship between LTC services and outcome variables, we use descriptive contingency tables. A categorised LTC variable is tabulated for each outcome variable. The table is created to display data for any outcome measure (number of events and incidence rate) and subcategories of LTC services (control period, training in LTC services, first year with constant LTC discussions, second and following years with constant LTC discussions). Most LTC services are rendered among families with school-aged children. Hence, similar analyses will be performed that separate data into subsamples according to age. Stratified analyses will include age groups of 0–6 and 7–17 years.

There are background differences between municipalities. To control for potential confounding, we use we use adjustment for municipal categories. For any given outcome, regression analysis involves the group-

specific incidence rates and the group-specific coverage data of LTC discussions. We apply a log-linear model in the analysis of incidence rate-ratio estimation. The results of statistical analyses are presented as incidence rate ratios with 90% confidence intervals and *p*-values.

Ethics and dissemination

The study design has been approved by the management of Oulu University Hospital in accordance with the guidelines of The Regional Ethics Committee of the Northern Ostrobothnia Hospital District in Oulu, Finland. The Regional Ethics committee concluded that this study does not require ethics approval.

The two rationales behind the present study design are: individual-level LTC intervention is difficult to measure in real life, because the framework of strengths and vulnerabilities applies to both the capacity of individuals and their social and physical ecologies. Moreover, in the Council of Oulu Region, all the municipal authorities autonomously make decisions on the implementation of LTC interventions. All data are treated and implemented according to national data security laws.

All parents are offered the opportunity to take part in an LTC discussion and are shown the structure of the discussion themes. If they agree, they make an appointment with the professional. The need for written consent was waived by The Regional Ethics Committee of the Northern Ostrobothnia Hospital District. This study is not research stipulated in the Finnish Medical Research Act (488/1999), which only applies to medical research involving intervention in the integrity of a person.

This paper outlines the LTC activities of the Council of Oulu Region's evaluation study, its design and data collection, and details on the implementation of the intervention. The LTC evaluation study uses a quasi-experimental trial design to evaluate the effectiveness of a community-level intervention that aims to improve children's well-being. This design is suitable in cases when the intervention cannot be delivered to all intervention areas at the same time.

The strengths of the study include the large number of participating municipalities and the multiple data collection stages. An LTC intervention in local child and family services may reduce the need for highly specialised child protection and child psychiatric services in northern Finland. The results from the study will contribute to the limited research available on the effectiveness of promoting children's well-being via an intervention programme that uses the child and family services approach.

This pragmatic evaluation of a community-led intervention in a real-life multi-professional setting is expected to provide information on adapting evidence-based methods for diverse municipalities. Child and family services are often renewed and directed in such ways that leave little, if any, resources for programme evaluation and outcome monitoring. In this study, independent regional investigators work together with local professionals to assess, in real-life settings, the association between the change in the local LTC intervention rate and the change in ecologic measures of children's health.

The LTC evaluation study in the Council of Oulu Region aims to expand our knowledge on the effectiveness of promoting children's health via an intervention programme that uses a multi-sectorial approach. At the same time, it improves co-operation between researchers and practitioners. The results can be useful for both the researchers and the managers leading the local reform of public child and family services. If the LTC intervention proves to be effective, the intervention programme can be distributed throughout Finland, as well as in other high-income countries.

List of abbreviations

LTCE = Let's Talk about Children Evaluation

LTC = Let's Talk about Children, a brief psychoeducational discussion with parents

LMT = Local Management Team

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Authors' contributions

VK and JJ obtained funding for the study. JJ further developed the intervention. VK designed the ecologic part of the study. HE and AP contributed to the study design. VK wrote this paper. All authors drafted and approved the final version of the manuscript.

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Competing interests: The authors declare that they have no competing interests.

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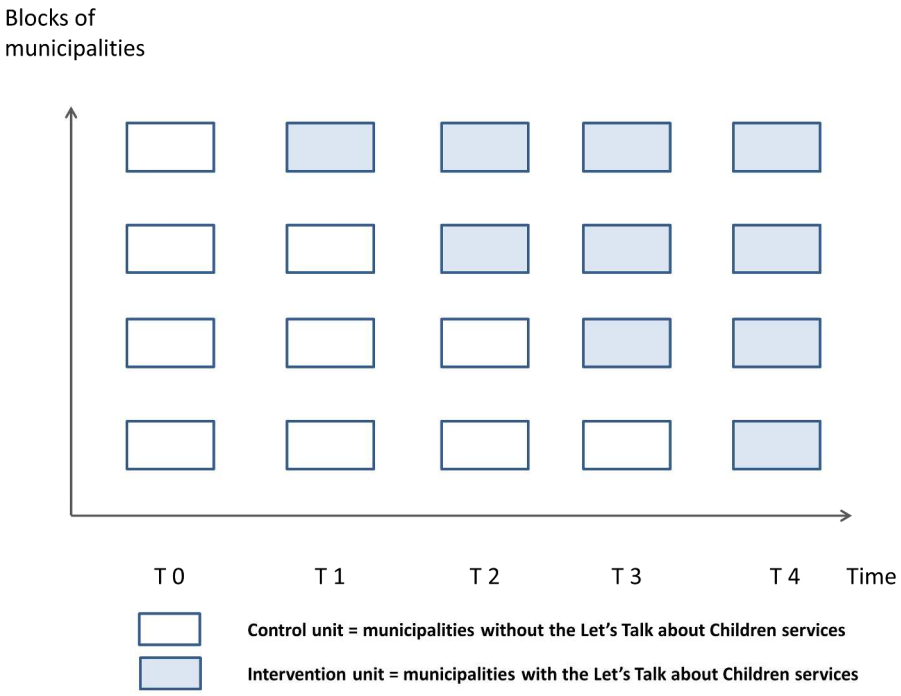
Figure legends

Figure 1 Design of present study. Blocks of municipalities represent groups of intervention areas. Each time point (T0, T1, T2, T3, or T4) represents a data collection point. Each unit (control or intervention) represents one time period for one block of municipalities.

Figure 2 Data collection stages for the Let's talk about the children evaluation study.

Figure 3 Gantt diagram of the Let's talk about the children evaluation study.



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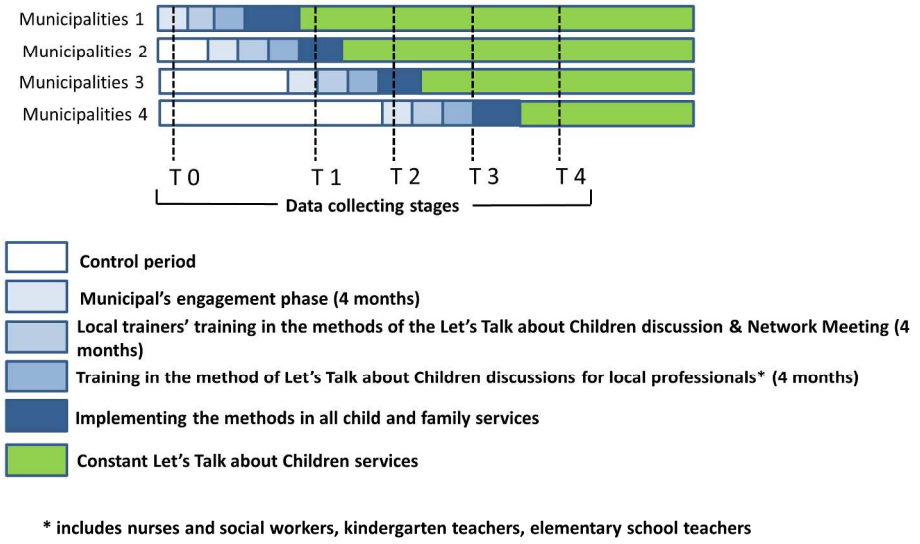

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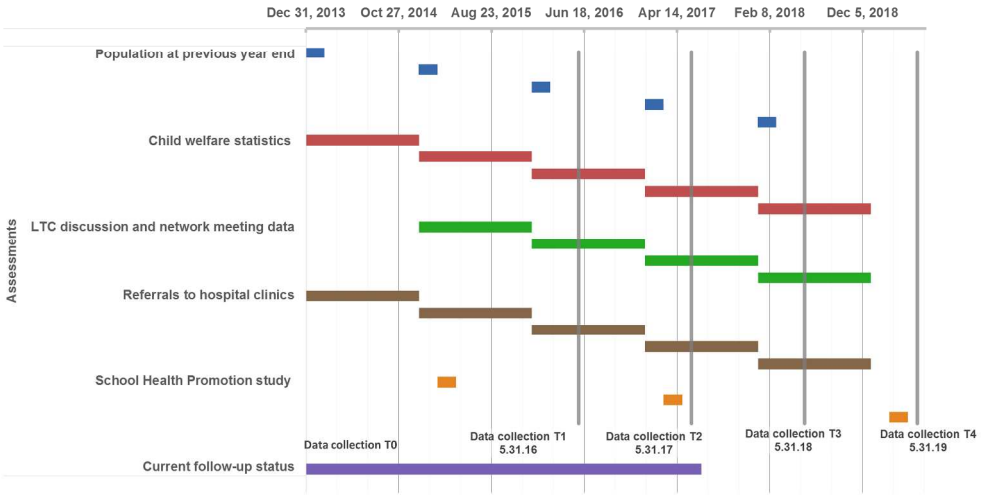

Figure 3 Gantt diagram of the Let's talk about the children evaluation study.

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6-10
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	n/a
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*12-14*
Bias	9	Describe any efforts to address potential sources of bias	14-15
Study size	10	Explain how the study size was arrived at	n/a
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	n/a
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	15-16
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	

		(*e*) Describe any sensitivity analyses	Page no results are shown
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Ethics and dissemination			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17
Generalisability	21	Discuss the generalisability (external validity) of the study results	n/a
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	18-19